2024 Current Fiscal Year Report: Clinical Laboratory Improvement Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

3. Committee or Subcommittee	3b. GSA Committee No.
Clinical Laboratory Improvement Advisory Committee	826

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	02/19/2022	02/19/2024	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No	42 U.S.C. 217a	

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 U.S.C. 217a	02/28/1992	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Clinical Laboratory Improvement Advisory Committee (CLIAC), hosted by the Centers for Disease Control and Prevention (CDC) in collaboration with the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA), provides scientific and technical advice to the Department of Health and Human Services (HHS). CLIAC provides timely and relevant advice and recommendations for refining and revising the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and addressing new clinical laboratory

testing quality issues to meet the changing needs of a dynamic health care system. Its role and functions are in the CLIA regulations (42 CFR part 493.2001) to meet the CLIA statutory requirement for consultation with private organizations and public agencies [42 USC 263a section 353 (q)]. Laboratory certificate fees support CLIAC through an interagency agreement between CMS and CDC, not through congressional appropriation. As of September 30, 2023, CLIAC has provided a total of 210 recommendations, which include 43 recommendations in the fiscal year 2023. Recent recommendations have addressed the laboratory workforce, the need for expanded regulatory oversight of CLIA Certificate of Waiver and Certificate for Provider-performed Microscopy (PPM) Procedures sites, the revision of the CLIA regulations to reflect current laboratory testing practices, and the laboratory's role in advancing health equity. In the fiscal year 2024, CDC, CMS, and FDA will work together to assemble three new workgroups. The Next Generation Sequencing (NGS) Workgroup was recommended by CLIAC in 2021 to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatic data analysis and interpretation to produce test results that inform clinical decision-making. The workgroup is charged with providing input to CLIAC for consideration in making recommendations to HHS on education, training, experience, and competencies that CLIA should require to qualify personnel performing next-generation sequencing bioinformatic data analysis and interpretation. The Biosafety Workgroup will be convened as a result of discussions during the CDC Town Hall Meeting on Laboratory Biosafety held on June 24, 2022. The workgroup is charged with providing input to CLIAC for consideration in making

recommendations to HHS on the potential additions to the CLIA regulations and the need for solutions that will improve the safety of laboratory professionals, their colleagues, and the environment. The workgroup will bring together diagnostic instrument manufacturers, clinical and public health laboratory professionals, federal partners, and industrial hygienists to provide input to CLIAC on solutions that will provide a safe working environment for the nation's clinical and public health laboratories. The Health Equity: The Role of the Clinical Laboratory Workgroup was recommended by CLIAC in April 2023 to determine how the clinical laboratory can contribute to health equity and population health and to closing racial/ethnic inequities in disease conditions with substantive disparities in incidence, prevalence, and outcomes. The scope is to be chronic kidney disease and its contributing factors, including social determinants of health, including examining barriers to closing these inequities. Other CLIAC discussions and recommendations provide guidance and support for policy and research projects, such as emerging technologies in clinical and public health laboratories, laboratory data exchange and harmonization, efforts to address the CLIA top ten laboratory deficiencies, the role of the laboratory in diagnostic and antimicrobial stewardship, the standardization of test result communication, the use of artificial intelligence in the clinical laboratory, and the need for curated reference materials for use in laboratory method validations.

20b. How does the Committee balance its membership?

The Committee consists of 20 members who are knowledgeable in the fields of microbiology (including bacteriology, mycobacteriology,

mycology, parasitology, and virology); immunology (including histocompatibility); chemistry; hematology; pathology (including histopathology and cytology); genetic testing (including cytogenetics); representatives from the fields of medical technology, bioinformatics, public health, and clinical practice; and consumer representatives. This representation is accompanied by an equal emphasis on diversity and qualified females and minorities are represented. The Committee also consists of three non-voting ex officio members and a non-voting liaison representative from the Advanced Medical Technology Association, which plays an important role in interacting and coordinating activities relating to the development of new devices/technology.

20c. How frequent and relevant are the Committee Meetings?

The Committee meets at least once per year. The Committee continues to play a critical role in recommending changes to CLIA program policy, standards, and guidelines by providing direction on the policy and procedures used in the development of and modifications to the CLIA regulations, the identification and prioritization of significant research data gaps, and continued evaluation of the procedures used in the implementation and administration of the program.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Clinical laboratories are the backbone of the healthcare system and provide the foundation for accurate and timely diagnosis, prevention, and control of disease to improve the health and safety of Americans. Approximately 15.76 billion laboratory tests are performed in the U.S. each

year, with at least one out of three patient encounters involving the ordering of one or more clinical laboratory tests; the volume of U.S. clinical laboratory testing is increasing at an average of 6-10% per year, and the scope of testing is becoming increasingly complex. Over the past 30 years since the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the number of FDA-cleared or approved tests has increased by more than 400% resulting in a need to ensure that the nation's over 322,000 CLIA-certified laboratories can accurately and reliably conduct testing and report results. CLIAC is the only Federal advisory committee that provides scientific and technical advice and guidance related to laboratory testing quality and practices to HHS and its agencies, including CDC, CMS, and FDA. CLIAC's advice, recommendations, and guidance are crucial, and CLIAC has made recommendations for HHS to update CLIA regulations for laboratory testing and personnel that have not been updated since 1992. CDC, CMS, and FDA are working together to act on these recommendations to revise the CLIA regulations; future CLIAC recommendations will provide additional guidance to HHS regarding both regulatory and non-regulatory actions needed for ensuring quality and safe laboratory practices. The Committee is essential for providing HHS with timely and relevant advice and recommendations for refining and revising the CLIA regulations and addressing issues of clinical laboratory testing quality to meet the changing needs of a dynamic healthcare system.

20e. Why is it necessary to close and/or partially closed committee meetings?

During fiscal year 2023, all CLIAC meetings were open to the public.

21. Remarks

No formal reports are required in the charter; the Committee provides advice and recommendations through various means other than formal reports. Monique Spruill, CMS ex officio resigned on 5/15/2022 and Gregg Brandush, CMS ex officio was appointed on 5/16/2022. Heather Duncan start date (SGE) (start date is 11/22/2020 - end date 12/30/2022 (served an additional 180 days from 6/30/2022 to 12/30/2022). Susan Gross (SGE) (start date 9/26/2018 - end date 12/30/2022 (served an additional 180 days from 6/30/2022 to 12/30/2022); Lee Hilborne (SGE) (start date 9/20/2018 - end date 12/30/2022 (served an additional 180 days from 6/30/2022 to 12/30/2022); Edwa King (SGE) (start date 7/1/2021 - end date 6/30/2025 (resigned on 5/23/2022); Valerie Ng (SGE) (start date 7/01/2020 - end date 12/30/2022 (served an additional 180 days from 6/30/2022 to 12/30/2022); and Gregory Sossman (SGE) (start date 9/20/2018 - end date 12/30/2022 (served an additional 180 days from 6/30/2022 to 12/30/2022).

Designated Federal Officer

Reynolds Mathewson Salerno Director, Division of Laboratory Systems

Committee Members	Start	End	Occupation	Member Designation
Black, Michael	07/01/2021	06/30/2025	Assistant Vice President, Clinical Laboratory System	Special Government Employee (SGE) Member
Brandush, Gregg	05/16/2022	05/15/2027	Director, Division of Laboratory Services, CMS	Ex Officio Member
Chapin, Kimberle	07/01/2021	06/30/2025	Medical and Scientific Affairs, Cepheid	Special Government Employee (SGE) Member

Crawford, James	07/01/2021	06/30/2025	Senior Vice President for Laboratory Services	Special Government Employee (SGE) Member
Edgerton, Mary	07/01/2020	06/30/2024	Associate Professor, Department of Pathology	Special Government Employee (SGE) Member
Koch, David	07/01/2021	06/30/2025	Director, Clinical Chemistry, Special Chemistry, Toxicology, and Point-of-Care Testing	Special Government Employee (SGE) Member
Leaumont, Collette	03/05/2018	03/04/2024	Associate Director for Science, DLS	Ex Officio Member
Patel, Nirali	07/01/2020	06/30/2024	Physician, Tempus Labs	Special Government Employee (SGE) Member
Pentella, Michael	07/01/2020	06/30/2024	Physician, Tempus Labs	Special Government Employee (SGE) Member
Stenzel, Timothy	10/16/2020	10/15/2025	Director Office of In Vitro Diagnostics and Radiological Health, FDA	Ex Officio Member
Tuthill, J. Mark	07/01/2021	06/30/2025	Division Head, Pathology Informatics	Special Government Employee (SGE) Member
Watkins, R. W. (Chip)	07/01/2020	06/30/2024	Chief Medical Officer	Special Government Employee (SGE) Member

Number of Committee Members Listed: 12

Narrative Description

The intention of the CLIA statute and its implementing regulations is to ensure the quality and reliability of medical tests performed by clinical laboratories throughout the nation. The Committee's advice and recommendations relative to the CLIA program are consistent with and supportive of CDC's vision of equitably protecting health, safety, and security.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	
Major policy changes	
Advance in scientific research	
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

Implementation of laws or regulatory requirements

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

N/A

What is the approximate Number of recommendations produced by this committee for the life of the committee?

210

Number of Recommendations Comments

Recommendations address general issues related to improvement in clinical laboratory quality and laboratory medicine practice. Recommendations generally provide guidance to assure quality laboratory testing and support for policies, studies, and evaluation activities. There were 43 recommendations for the fiscal year 2023. During the November 9-10, 2022 meeting, there were nine recommendations. Three recommendations related to laboratory workforce: (1) CLIAC recommends that CDC, CMS, and other federal laboratory partners implement technology alternatives (e.g., virtual reality) to current in-person activities (e.g., training, learning, competency assessment) to meet regulatory requirements (e.g., CMS, OSHA, DOT); (2) CLIAC recommends CDC examine opportunities for funding to support the educational pipeline for the laboratory profession, including but not limited to tuition benefits and loan forgiveness for students and supporting institutions of learning and sites of clinical training with special attention to recruitment and admission of students from minority and underrepresented populations; and (3) To improve health equity and public health, CDC should partner with industry and philanthropic organizations to have virtual reality (VR) tools and resources accessible for clinical laboratory training. One recommendation related to CLIAC deliberations on the CLIA Certificate of Waiver and Provider-performed Microscopy Procedures Workgroup report is that the CLIA law be opened to allow oversight of CLIA Certificate of Waiver testing sites. Five recommendations related to CLIAC deliberations on the CLIA Regulatory Assessment Workgroup related to updating the CLIA regulations to include a definition for “materials derived from the human body” and “test system”, guidelines used when assessing the applicability of a site’s CLIA certificate when evaluating whether remote testing requires an additional CLIA certificate for staff working at a remote location, a new certificate type for an entity manipulating information received from and returned to the clinical laboratory for inclusion in the patient report or for patient care, and recommends that FDA include, whenever possible, controls for specimen adequacy, integrity, and human origin for authorization of self-collection devices. During the April 12-13, 2023 CLIAC meeting, there were 34 recommendations. Three recommendations related to the laboratory’s role in advancing health equity: (1) CLIAC recommends the formation of a workgroup to determine how the clinical laboratory can contribute to health equity and population health and to closing racial/ethnic inequities in disease conditions with substantive disparities in incidence, prevalence, and outcomes. The scope is to be chronic kidney disease and its contributing factors, including social determinants of health, including examining barriers to closing these inequities; (2) CLIAC recommends that the FDA evaluate instruments that cannot implement the CKD-EPI 2021 eGFR race-free equation, standardize the creatinine methods, and report back to CLIAC during the November 2023 meeting; and (3) CLIAC recommends that the CDC’s Division of Laboratory Systems work with partners, such as professional organizations, community groups, and others, to provide outreach and training related to the CKD-EPI 2021 eGFR

race-free equation. Two recommendations were made related to CLIAC deliberations on the CLIA Certificate of Waiver and Provider-performed Microscopy Procedures Workgroup report: (1) CLIAC recommends that more information is needed about CLIA Certificate for Provider-performed Microscopy Procedure sites and suggests the expansion of the CMS PPM Project; and (2) CLIAC recommends that CLIA regulations be modified to implement routine inspection for CLIA Certificate for Provider-performed Microscopy sites. There were 29 recommendations made related to CLIAC deliberations on the CLIA Regulatory Assessment Workgroup related to updating or modifying CLIA Subpart K – Quality Systems for Nonwaived Testing.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
80%

% of Recommendations Fully Implemented Comments
167 completed recommendations and 1 recommendation has no action/completed.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
20%

% of Recommendations Partially Implemented Comments
There are 42 recommendations with partial implementation.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
Yes, through agency updates provided at the beginning of each Committee meeting. A recommendations table with the date of the recommendation, category, the recommendation text, and current status is updated and can be found at https://www.cdc.gov/cliac/meeting.html.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐

Issued new regulation	☐
Proposed legislation	☑
Approved grants or other payments	☐
Other	☑

Action Comments

In fiscal year 2023, in response to recommendations made by CLIAC on histopathology and remote review of histopathology and cytology slides and images, CMS and CDC published the Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 Request for Information (RFI) on July 13, 2023 as part of the CY2024 Physician Fee Schedule proposed rule (CMS-1784-P) (https://www.federalregister.gov/documents/2023/08/07/2023-14624/medicare-and-medicaid-prc The RFI received 53 public comments. CDC and CMS will work in the fiscal year 2024 to address the comments that may result in future rulemaking. In response to a CLIAC recommendation made during the November 2019 meeting on remote selection, interpretation, and reporting of patient results, CMS during the COVID-19 pandemic, allowed laboratories to utilize temporary testing sites for remote review and reporting of laboratory data/slides/images as long as specific criteria are met (https://www.cms.gov/files/document/qso-20-21-clia.pdf-0). In May 2023, to ensure the accuracy, reliability and timeliness of laboratory results, CMS will continue to exercise enforcement discretion to permit pathologists and other laboratory personnel to review digital laboratory data, digital results and digital images (“digital materials”) remotely, without obtaining a separate CLIA certificate for the remote testing site, provided that the designated primary site or home base has such a certificate (using the address of the primary site) and the work being performed at the remote testing site falls within the specialties/subspecialties under the primary site’s certificate (https://www.cms.gov/files/document/qso-23-15-clia.pdf). In response to a CLIAC recommendation on laboratory data exchange during the October 28-29, 2020 meeting, the CDC's Division of Laboratory Systems formed a group to begin strategic planning for the process to improve existing laboratory information system infrastructures. In response to a CLIAC recommendation based on information provided by the CLIA Regulatory Assessment Workgroup during the November 2022 CLIAC meeting, FDA will consider the recommendation for inclusion of controls for specimen adequacy, integrity, and human origin for authorization of self-collection devices whenever possible. In fiscal year 2023, the CDC had several accomplishments related to three laboratory workforce recommendations made during the November 2022 meeting, including: - CDC's Division of Laboratory Systems released, OneLab VR, a virtual clinical laboratory environment, in April 2023 for free on the STEAM gaming platform. CDC’s VR dissemination program has

sent VR training equipment to 30+ US clinical and public health laboratories and is enrolling additional partner laboratories on a rolling basis. CDC will pilot OneLab VR as a live training tool in US laboratories in 2023-2024. OneLab VR is one of 7 components of CDC's OneLab Initiative. - With American Rescue Plan funds, CDC supports fellowships and internships in state, local, and territorial public health laboratories in collaboration with APHL. In September 2023, CDC's OneLab Initiative provided $1M to fund MLT and MLS certifications through an existing cooperative agreement. CDC is exploring additional opportunities to recruit, train, and retain a diverse laboratory workforce in 2023 and beyond. - CDC's OneLab Initiative is exploring a new partnership in collaboration with the CDC Foundation to have VR tools and resources accessible for clinical laboratory training. In response to two recommendations on the laboratory's role in advancing health equity made during April 2023, CDC's Division of Laboratory Systems has engaged the National Kidney Foundation to explore outreach and training related to the CKD-EPI 2021 eGFR race-free equation. Also, the FDA is collecting information on instruments that cannot implement the CKD-EPI 2021 eGFR race-free equation to standardize the creatinine methods and plans to report back to CLIAC in fiscal year 2024.

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments
N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☐
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☐
Other	☐

Access Comments
https://www.cdc.gov/cliac/